

REMARKSStatus of the Claims

Applicants had previously elected Group II (claims 15, 16, 24 and 26) without traverse for further examination. Claims 69-104, directed to the same group, had previously been added.

Applicants appreciate the Examiner's reconsideration of the restriction requirement. As a result of this reconsideration, the claims of Group I (claims 1-14, 17-23, 25, 27-39, and 68) have been rejoined. Claims 40-67 remain withdrawn.

Applicants have amended claims 1, 3-5, 7, 8, 10, 13, 14, 21, 22, 24, 25, 27, 29, 32, 33, 78, 82, 92, 95 and 97 for the reasons discussed herein. Claim 2, 9, 68, 79 and 93 have been canceled without prejudice.

Claims 1, 3-8, 10-39 and 69-78, 80-92 and 94-105 thus remain in this case for further examination.

Amendments to the Specification

Applicants have amended the specification to include all cross-references to prior-filed applications to which the present application claims priority, and to indicate that the parent application is now abandoned.

Per the Examiner's suggestion, applicants have also amended certain paragraphs in the specification to delete references to URLs.

No new matter has been added by way of any of these amendments. Applicants request their entry.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-39 and 68-105

Claims 1-39 and 68-105 were rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. In particular, the Examiner contends that the specification "does not reasonably provide enablement for use of any source of host cell from a first species, nor the use of any organism besides a mammalian species, nor the use of a non-enucleated oocyte." (Office Action at page 4.) The Examiner also contends that "cross-species nuclear transfer can not result in a rejuvenated cell." (Id. at page 7.) Applicants traverse this rejection.

However, solely to advance this case, applicants have amended certain claims to exclude the alleged non-enabled subject matter. This cancellation is made without prejudice, and applicants expressly reserve their right to pursue the cancelled subject matter in one or more future continuation or divisional applications.

Specifically, applicants have amended claims 1, 8, 21, 22, 25, 27, 29, 78 and 92 to require that (a) both the

donor cell and the recipient cell are mammalian, (b) both the donor cell and the recipient cell are derived from the same mammalian species, and (c) the recipient cell is enucleated. Support for these amendments can be found at, for example, page 29-33 of the specification.

Claims 25-39

With respect to claims 25-39, the Examiner also contends that "there is no teaching in the specification nor the art of record which demonstrates the necessary guidance needed to transplant a developing embryo into a species with a different genetic background." (Id. at page 7.) Applicants traverse.

However, solely to advance this case, applicants have amended claims 25 and 27 to make clear that the embryo or embryonic stem cell are introduced into a recipient female of the same mammalian species. Support for these amendments can be found at, for example, page 30 of the specification.

Claim 68

The Examiner has rejected claim 68 for failing to recite any method steps. Solely to advance the prosecution of this case, applicants have canceled claim 68 without prejudice.

For at least the reasons presented above, applicants request that the rejections of claims 1, 3-8, 10-39 and 69-78, 80-92 and 94-105 under 35 U.S.C. § 112, first paragraph, be

reconsidered and withdrawn. The rejections of claims 2, 9, 68, 79 and 93 are moot in view of their cancellation.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-28, 30-33, 68-71, 82-84 and 94-96 were rejected under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. Applicants traverse this rejection.

For the claims listed below, and the claims that depend therefrom, applicants have overcome or obviated their respective rejections for the reasons presented below:

Claim 1: The Examiner has rejected this claim, alleging that the metes and bounds of "rejuvenated" is unclear. Applicants have amended claim 1 to make clear that rejuvenation of the isolated cell refers to its increased number of remaining population doublings relative to the number of remaining population doublings in the primary cell used as the source of the transfer. This definition can be found at, for example, page 15 of the specification.

Claims 3, 32, 33 and 94: The Examiner has rejected these claims because of an alleged lack of clarity regarding the source of the control teratoma. Applicants have amended claims to make clear that the recited control teratoma, animal, or cells are derived from cells that were not generated by nuclear transfer.

Claim 4: The Examiner has rejected this claim because it depends from itself. Applicants have amended this claim to correct this error.

Claim 7, 14, 82 and 95: The Examiner has rejected these claims as being allegedly vague and unclear, stating that it is unclear which cell includes the recited alteration to the genome. Applicants have amended these claims to more clearly identify the cell that includes the alteration to the genome, and to make clear that the genomic alteration is present prior to transfer.

Claim 8: The Examiner has rejected this claim because of an alleged lack of clarity regarding the second recited teratoma. Applicants have amended this claim to make clear that the second teratoma is not a required product of the claimed method, but merely describes the characteristics of a same-age control teratoma to which the isolated cell is compared.

Claim 13: The Examiner has rejected this claim because of an alleged lack of clarity regarding the recited tissue. Applicants have amended this claim to make clear that the tissue is intended for use in transplantation.

Claim 25: The Examiner has rejected this claim because it is allegedly unclear and confusing regarding the genotype of the animal of step (d). Applicants have amended this claim to make clear that the newborn animal has the same genotype as the cell of claim 24, as recited in the preamble.

Claim 27: The Examiner has rejected this claim for alleged lack of an active step. Applicants have amended this claim to recite the steps of nuclear transfer.

Claim 68: The Examiner has rejected this claim for alleged lack of an active step. Applicants have canceled this claim, thereby obviating this objection.

Claim 84: The Examiner has rejected the term "substantially the same." Applicants have canceled the offending term without prejudice.

Applicants submit that these amendments and remarks have overcome and/or obviated all of the rejections under 35 U.S.C. § 112, second paragraph. Reconsideration and withdrawal of these rejections is therefore respectfully requested.

Rejections Under 35 U.S.C. § 102

Claims 1-39 and 68-105 were rejected under 35 U.S.C. §§ 102(a) and (e) as being allegedly anticipated by Strelchenko (U.S. Patent 6,011,197) or Damiani (U.S. Patent 6,258,998) as evidenced by Evans (Nature Genetics 23, pp 90-93, 1999). Applicants traverse these rejections.

The Examiner contends that both Strelchenko and Damiani teach methods of nuclear transfer, and that both teach methods of generating an animal in which a heterologous sequence is introduced. (Office Action at page 12.) The Examiner thus contends that (1) applicants' claimed methods are

anticipated by the cited references and (2) applicants' claimed products (i.e., cells, animals, etc.) are anticipated or inherently anticipated by the cited references.

Applicants disagree. All of the applicants' claims include at least one of the following features, neither of which is disclosed expressly or inherently in the cited references.

First, the methods of claims 1, 8, 29 and 78 all require the formation, isolation, and separation of a teratoma, and from which the resultant cells are isolated. Applicants submit that the formation, isolation, and separation of such a teratoma is neither expressly nor inherently disclosed in any of the cited references.

Second, claims 1, 8, 21, 22, 27, 29, 37, 78 and 92 all require that the donor cell used in the nuclear transfer be senescent or near-senescent. Applicants submit that the use of such senescent or near-senescent cells for nuclear transfer donors is neither expressly nor inherently disclosed in any of the cited references. Thus, although the cited references may refer to cells, etc. produced by nuclear transfer, none of these references disclose cells, etc. that resulted from the use of senescent or near-senescent cells as a donor for nuclear transfer.

For at least the above reasons, applicants submit that the pending claims are not anticipated by the cited references, as the cited references do not disclose, either

expressly or inherently, all of the features of applicants' claims. Reconsideration and withdrawal of these rejections is respectfully requested.

Provisional Statutory-Type Double Patenting

Claim 1 was provisionally rejected under 35 U.S.C. § 101 over claim 1 of co-pending U.S. Patent Application No. 11/079,930 ("the '930 application").

Applicants have obviated this rejection by amending claim 1 herein, so that amended claim 1 is no longer co-extensive with the currently pending claim 1 in the '930 application. Accordingly, reconsideration and withdrawal of this rejection is requested.

Provisional Obviousness-Type Double Patenting

Claim 1 was provisionally rejected under the judicially-created doctrine of obviousness-type double patenting over claims 1 and 4-6 of U.S. Patent 6,808,704. In response, applicants traverse.

Nonetheless, applicants will address this rejection upon the indication of otherwise allowable subject matter in this application.

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Conclusion

Applicants respectfully submit that all of the pending claims are in form for allowance, but expressly reserves his right to argue the patentability of the subject matter of any one of the dependent claims in a future proceeding. If the Examiner believes, however, that any matters remain outstanding, applicant respectfully requests that the Examiner call the undersigned.

Respectfully submitted,



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